IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

HILDA CAMPBELL, et al.,	*	
Plaintiffs,	*	
v.	*	Civil Action No. GLR-20-1356
ETHICON, INC., et al.,	*	
Defendants.	*	

***

MEMORANDUM OPINION

THIS MATTER is before the Court on Defendants Ethicon, Inc. and Johnson & Johnson's (collectively, "Defendants" or "Ethicon") Motion for Summary Judgment (ECF No. 73). The Motion is ripe for disposition, and no hearing is necessary. See Local Rule 105.6 (D.Md. 2021). For the reasons outlined below, the Court will grant in part and deny in part Ethicon's Motion for Summary Judgment.

I. BACKGROUND

A. Campbell's Symptoms and Treatment

Hilda Campbell ("Campbell") began struggling with stress urinary incontinence in 2012. (Campbell's Dep. Tr. ["Campbell Dep."] at 111:15–22, ECF No. 73-1). Campbell found that she was unable to enjoy several of her hobbies, including swimming, gardening, hiking, playing tennis, and cycling, because she would experience accidental leaks. (Campbell Dep. at 112:6–113:18). She eventually started wearing pads to help protect her clothing. (Id. at 114:15–23). Campbell would also take multiple showers a day and change her underwear frequently because of her symptoms. (Id. at 115:4–8).

On June 17, 2013, Campbell, who had a history of unrelated back pain, visited Dr. Cynthia Moorman for a consult. (Med. Rs. at 2; Hilda Campbell Decl. ["Campbell Decl."] ¶ 4, ECF No. 74-1). Moorman noted that Campbell would experience leaks with activities but indicated that she was not leaking during sex and she did not use pads at night. (Med. Rs. at 2). On September 27, 2013, Moorman implanted the TVT mesh product to treat Campbell's stress urinary incontinence and intrinsic sphincteric deficiency in Frederick, Maryland. (Id. at 5). Moorman did not note any complications during the procedure. (See id. at 5–6).

After the surgery, Campbell experienced "pain and injury including vaginal pain, pain during sex, and incontinence." (Campbell Decl. ¶ 3). In July 2017, Dr. Daniel Gruber performed surgery to excise the TVT product in Bethesda, Maryland. (Campbell Dep. at 11:25–12:4; Pl.'s Fact Sheet at 6).[1]

Campbell indicates that if she knew that her "medical history of back pain caused [her] to have a higher risk of mesh failure, [she] would not have gone forward with [the implant] procedure." (Campbell Decl. ¶ 6). Further, she contends that if she had known the risks of "permanent sexual pain and dangerous potential complications in revising the mesh," she likewise would not have had the surgery. (Id. ¶ 7).

[1] Neither party attached Gruber's operative report to their briefing, so the few details regarding the procedure are pulled from the Fact Sheet Campbell submitted in the related multi-district litigation in West Virginia.

B. Moorman's Testimony

Moorman testified that she began performing procedures using TVT mesh products in the late 1990s. (Cynthia Moorman Dep. ["Moorman Dep."] at 24:17–20, ECF No. 73-4). Since then, she has performed hundreds of implant procedures and she continues to do so today. (Id. at 24:23–25:3).

Moorman testified that she relies on her training, presentations, journal articles, FDA warnings, and the American Urological Association to inform her of the risks affiliated with mesh surgeries. (Id. 60:13–62:4). She stated that "[a]s time goes on there are more risks that come to light," and she does her best to keep up with those risks as they come out in the literature and in warnings. (Id. at 80:10–21). Nonetheless, she does not rely on Ethicon "much" to inform her of the risks of the mesh. (Id. at 85:24–86:10). Moorman stated that her opinion on the risk/benefit analysis regarding TVT slings has not changed much over time. (Id. at 92:20–93:2). She "still ha[s] the same categorization" of patients to whom she still recommends mesh surgery. (Id.). She indicated that she likes certain kinds of mesh, including the mesh made by Ethicon, because in her experience it has a lower chance of recurrence. (Id. at 74:25–75:18). Moorman testified that she knew "everything that is on [the TVT mesh's] risk profile" "from day one." (Id. at 93:13–24).

When she performed Campbell's surgery in 2013, Moorman was personally aware of the risks of dyspareunia, or pain during sex, vaginal pain, scarring, infection, urinary problems, organ or nerve damage, bleeding, wound complications, inflammation, fistula formation, muscular or extremity problems, and the need for additional surgeries. (Id. at 71:20–74:22). Moorman decided to perform Campbell's surgery because she believed the

potential benefits outweighed the potential risks. (Id. at 77:8–13). Indeed, she would not have performed the surgery if she believed otherwise. (Id.).

During the deposition, counsel for Plaintiffs posed a hypothetical regarding the impact of preexisting back pain on the failure rate for TVT implantation surgery. (Id. at 106:21–110:6). Counsel and Moorman had the following exchange:

> [COUNSEL FOR PLAINTIFFS]: If the Ethicon TVT had been contraindicated for people with back pain, is it fair to say that that is something that you would have specifically asked your patients about?
>
> [MOORMAN]: Well, yeah. Yes.
>
> [COUNSEL FOR PLAINTIFFS]: And if the Ethicon TVT had been contraindicated for people with back pain and Ms. Campbell had informed you that she had a history of back pain, is it fair to say that's something that would have gone into your risk/benefit decision with Ms. Campbell?
>
> [MOORMAN]: I would have discussed it with her. Yeah, I would have discussed it with her because it would depend on, you know, what kind of back pain, what is the back pain from. I'm sure that makes a difference because a lot of people have back pain. So yeah. I would have discussed it, absolutely. I can't say I wouldn't have done it. It just depends. A lot of patients have back pain, but yeah.
>
> [COUNSEL FOR PLAINTIFFS]: And again, it's a hypothetical because Ethicon never warned and contraindicated of back pain, right?
>
> [MOORMAN]: Not that I know of. Not that I know of. I guess there could be stuff. I don't read absolutely everything but the information I have read and been taught, no.[2]

(Id.). Moorman explained, however, that Campbell never told her that she experienced prior back pain. (Id. at 107:9–108:16).

[2] For concision, the Court has omitted defense counsel's occasional objections. (See Moorman Dep. at 106:21–110:6).

Finally, Moorman said that she stood by her decision to implant the TVT mesh in Ms. Campbell "[b]ased on the time in 2013." (Id. at 148:17–19).

C. Expert Opinions

Dr. Bruce Rosenzweig provided both a case-specific and a general opinion on behalf of Campbell. In his case-specific report, Rosenzweig provided the following opinion on the design of the product:

> 1. As a result of the implantation of the TVT mesh product, including the mesh characteristics discussed below and within my general expert report, and the subsequent reactions and surgical revision, Ms. Campbell has sustained the following injuries, which are most likely permanent in nature: need for revision surgery, pelvic and suprapelvic pain, voiding dysfunction and mixed urinary incontinence.
>
> 2. It is my opinion, to a reasonable degree of medical and scientific certainty, that the debilitating injuries suffered by Ms. Campbell, which are listed above, were directly caused by the TVT mesh device, including the following polypropylene mesh characteristics: (a) degradation of the mesh; (b) chronic inflammation and chronic foreign body reaction; (c) mesh that was never meant to be implanted inside the human body and is incompatible with the naturally occurring condition of the vagina including peroxides and bacteria; (d) deformation, rigidity of the mesh, fraying, roping, cording, curling and sharp edges of the mesh; (e) loss of pore size with tension; (f) fibrotic bridging leading to scar plate formation and mesh encapsulation; (g) shrinkage/contraction of the encapsulated mesh; and (h) the difficulty and/or impossibility of removing the devices; (i) migration.

(Case-Specific Expert Report Bruce Rosenzweig, M.D. ["Rosenzweig Case-Specific Rep."] at 18, ECF No. 74-5). Additionally, as to warning, Rosenzweig opined that Moorman was unable to provide "the necessary and required information to Ms. Campbell for an informed consent because Ethicon failed to fully reveal such information and failed

to fully evaluate said information prior to launch." (Id. at 22). Finally, Rosenzweig opined that there were safer alternative designs for the product, including the use of sutures "in a colposuspension procedure," an autologous fascia sling, an allograft sling, and a sling with less polypropylene. (Id. at 22–23).

Rosenzweig's one-hundred-page general report includes opinions on the design of the mesh, Ethicon's warnings in its Instructions for Use, Ethicon's failure to reveal "material facts about complication and conflict of interests regarding key studies" and marketing documents, and a risk/benefit analysis for the product. (See Rule 26 Expert Report Bruce Rosenzweig, M.D. ["Rosenzweig Gen. Rep."] at 3–4, ECF No. 74-6). Rosenzweig specifically opines that Ethicon's warnings were inadequate because Ethicon failed to warn of the following problems with the mesh:

> [D]isclose information to physicians in its [Instructions for Use] regarding characteristics of the old construction mesh (Prolene) that makes it unsuitable for its intended application as a permanent prosthetic implant for stress urinary incontinence, including that it is small pore, heavy weight mesh, it degrades over time, causes chronic foreign body reactions, fibrotic bridging, mesh contracture/shrinkage, fraying, particle loss, roping and curling of the mesh, that it deforms and the pores collapse with tension, that it is difficult or impossible to tension; that it tested positive for cytotoxicity and that . . . it is incompatible with strong oxidizers such as peroxides.

(Rosenzweig General Rep. at 4). Rosenzweig's summary of opinions does not reference anything regarding previous back pain or pain syndromes. (See generally id. at 3–4).

Campbell also obtained a general opinion from Scott Guelcher, Ph.D. (Expert Rep. Scott Guelcher, Ph.D. ["Guelcher Rep."], ECF No. 74-7). Guelcher, a chemical engineer,

provides opinions on design of the product and the risks associated with the materials used. (See id. at 3 (providing summary of opinions)). Guelcher also provides opinions on alternative designs, including autologous fascia, allograft, sutures, or mesh made from polyvinylidene fluoride. (Id. at 25–28).

D. Procedural History

On August 24, 2017, Campbell filed a short form Complaint in the multi-district litigation in the United States District Court for the Southern District of West Virginia. (ECF No. 1). Campbell's Complaint alleges: negligence (Count I); strict liability – manufacturing defect (Count II); strict liability – failure to warn (Count III); strict liability – defective product (Count IV); strict liability – design defect (Count V); common law fraud (Count VI); fraudulent concealment (Count VII); constructive fraud (Count VIII); negligent misrepresentation (Count IX); negligent infliction of emotional distress (Count X); breach of express warranty (Count XI); breach of implied warranty (Count XII); violation of consumer protection laws (Count XIII); gross negligence (Count XIV); unjust enrichment (Count XV); loss of consortium (Count XVI); punitive damages (Count XVII); and discovery rule and tolling (Count XVIII). (See Compl. at 4–5). Campbell's husband, John Campbell, joins as to the loss of consortium count only.

On March 15, 2018, Campbell submitted a Fact Sheet providing additional details regarding her claims. (ECF No. 7). On June 2, 2019, Ethicon filed a Motion for Partial Summary Judgment. (ECF Nos. 32 & 33). Ethicon also filed a Motion to Limit the Case-Specific Opinions and Testimony of Bruce A. Rosenzweig, M.D. (ECF Nos. 34 & 35). Campbell opposed both motions on June 13, 2019, and Ethicon filed Replies on June 24,

2019. (ECF Nos. 36–39). On May 19, 2020, the Southern District of West Virginia issued an Order indicating that discovery was complete and the matter was ready for trial. (ECF No. 40). On June 1, 2020, the case was transferred to this Court. (ECF No. 52).

On September 10, 2020, the Court noted that a settlement conference had been scheduled and denied without prejudice Ethicon's pending Motion for Partial Summary Judgment and Motion to Limit the Case-Specific Opinions and Testimony of Bruce A. Rosenzweig, M.D. (ECF No. 63). The Court indicated, however, that Ethicon could reinstate the motion should settlement discussions be unsuccessful. (Id.). On April 20, 2021, the parties filed a Joint Stipulation of Partial Voluntary Dismissal agreeing to dismiss Campbell's claims for manufacturing defect, which accounted for part of her negligence claims and all of her claims of strict liability – manufacturing defect (Count I – in part; Count II; Count XIV – in part), strict liability – defective product (Count IV), constructive fraud (Count VIII), negligent infliction of emotional distress (Count X), violation of consumer protection laws (Count XIII), and unjust enrichment (Count XV). (ECF No. 71). The Court approved the Stipulation and dismissed the claims the following day. (ECF No. 72).

On April 23, 2021, Ethicon filed a new Motion for Summary Judgment and Memorandum in Support. (ECF No. 73). The Campbells filed their Opposition on May 14, 2021. (ECF No. 74). In the Opposition, the Campbells agree to voluntarily dismiss the breach of warranty claims (Counts XI & XII), the separate punitive damage count (Count

XVII),[3] and the discovery rule and tolling count (Count XVIII).[4] Ethicon filed a Reply on June 1, 2021. (ECF No. 77).

II. DISCUSSION

A. Standard of Review

In reviewing a motion for summary judgment, the Court views the facts in a light most favorable to the nonmovant, drawing all justifiable inferences in that party's favor. Ricci v. DeStefano, 557 U.S. 557, 586 (2009); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986) (citing Adickes v. S.H. Kress & Co., 398 U.S. 144, 158–59 (1970)). Summary judgment is proper when the movant demonstrates, through "particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . admissions, interrogatory answers, or other materials," that "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(a), (c)(1)(A). Significantly, a party must be able to present the materials it cites in "a form that would be admissible in evidence," Fed.R.Civ.P. 56(c)(2), and supporting affidavits and declarations "must be made on personal knowledge" and "set out facts that would be admissible in evidence," Fed.R.Civ.P. 56(c)(4).

Once a motion for summary judgment is properly made and supported, the burden shifts to the nonmovant to identify evidence showing that there is a genuine dispute of

[3] The Campbells note that they are not waiving any argument for punitive damages at trial; rather, they are only agreeing to dismiss the separate count.

[4] Accordingly, the Court will grant judgment as to Counts XI, XII, XVII, and XVIII.

material fact. See Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586–87 (1986). The nonmovant cannot create a genuine dispute of material fact "through mere speculation or the building of one inference upon another." Othentec Ltd. v. Phelan, 526 F.3d 135, 140 (4th Cir. 2008) (quoting Beale v. Hardy, 769 F.2d 213, 214 (4th Cir. 1985)).

A "material fact" is one that might affect the outcome of a party's case. Anderson, 477 U.S. at 248; see also JKC Holding Co. v. Wash. Sports Ventures, Inc., 264 F.3d 459, 465 (4th Cir. 2001). Whether a fact is considered to be "material" is determined by the substantive law, and "[o]nly disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." Anderson, 477 U.S. at 248; accord Hooven-Lewis v. Caldera, 249 F.3d 259, 265 (4th Cir. 2001). A "genuine" dispute concerning a "material" fact arises when the evidence is sufficient to allow a reasonable jury to return a verdict in the nonmoving party's favor. Anderson, 477 U.S. at 248. If the nonmovant has failed to make a sufficient showing on an essential element of his case where he has the burden of proof, "there can be 'no genuine [dispute] as to any material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." Celotex Corp. v. Catrett, 477 U.S. 317, 322–23 (1986).

B. Analysis[5]

1. Failure to Warn

Campbell alleges that Ethicon is liable in negligence and strict liability for failure to warn of the risks of the TVT device. (Count I – in part; Count III; Count XIV – in part).[6] In her Opposition, she argues the Ethicon failed to warn her of the "higher risk for patients with chronic back pain" to develop complications from the TVT implant. (Pls.' Opp'n Defs.' Mot. Summ. J. ["Opp'n"] at 12, ECF No. 74). She contends that if she knew about that risk, she would not have proceeded with the procedure. (Id.).[7]

In Maryland, "[p]roducts liability law imposes on a manufacturer a duty to warn if the item produced has an inherent and hidden danger that the producer knows or should know could be a substantial factor in causing an injury." Morris v. Biomet, Inc., 491 F.Supp.3d 87, 103–04 (D.Md. 2020) (quoting Shreve v. Sears, Roebuck & Co., 166 F.Supp.2d 378, 413 (D.Md. 2001)). Negligence and strict liability concepts have "morphed together in failure to warn cases." Id. at 104 (quoting Gourdine v. Crews, 955 A.2d 769,

[5] The parties correctly agree that Maryland law applies. See Belanger v. Ethicon, Inc., No. 2:12-MD-02327, 2014 WL 346717, at *7 (S.D.W.Va. Jan. 30, 2014) ("[T]he choice of law that applies is the place where the plaintiff was implanted with the product."); Smith v. MTD Prods., Inc., No. CCB-19-1592, 2019 WL 5538273, at *2 (D.Md. Oct. 24, 2019) ("The lex loci delicti rule provides that 'the substantive tort law of the state where the wrong occur[s]' governs." (quoting Philip Morris v. Angeletti, 752 A.2d 200, 231 (Md. 2000))). Campbell was implanted with the TVT product in Frederick, Maryland, so Maryland law applies. (See Campbell Decl. ¶ 4).

[6] Campbell's failure to warn claim constitutes part of her negligence claims (Count I & Count XIV) and all of her strict liability – failure to warn claim (Count III).

[7] Campbell also indicates that she should have been warned of the risk of permanent sexual pain. (Opp'n at 12). She does not, however, argue that Ethicon's failure to warn of permanent sexual pain proximately caused her injuries. (Id. at 13). As such, the Court need not address it.

782 (Md. 2008)) (cleaned up). This is because "traditional concepts of duty, breach, causation, and damage are required for both causes of action." Id.

Ethicon contends that Campbell's failure to warn claim fails when applying the learned intermediary doctrine because Campbell cannot show that Moorman would have changed her decision to prescribe the TVT device if Ethicon provided her with a different, purportedly adequate warning, which is necessary to establish proximate cause. (Defs.' Mot. Summ. J. Mem. Supp. ["Mot."] at 7–13, ECF No. 73). Campbell responds that, under Maryland law, the learned intermediary doctrine does not apply because the warning was inadequate. She further requests that this Court adopt a new rule regarding the scope of evidence that the Court can consider when determining whether a warning is adequate. Finally, she responds that even if the learned intermediary doctrine applies, she has adduced sufficient evidence to create a triable issue on causation. (Opp'n at 10–13).

Accordingly, the parties raise two main issues. First, whether the learned intermediary doctrine applies to Campbell's case. Second, whether Campbell has presented sufficient evidence to create a jury issue on proximate causation. As the Court's resolution of the first question is dispositive, it need not address proximate causation.

The learned intermediary doctrine addresses to whom the duty to warn extends. See Gourdine, 955 A.2d at 776. The doctrine provides that a manufacturer need only provide an adequate warning to the patient's prescribing physician of the risks attendant to the product used. Ames v. Apothecon, Inc., 431 F.Supp.2d 566, 572 (D.Md. 2006). The natural corollary, of course, is that the manufacturer has no duty to warn the patient directly. Lee v. Baxter Healthcare Corp., 721 F.Supp. 89, 94–95 (D.Md. 1989). "If the physician has

been adequately warned, he is a 'learned intermediary' because he is in the 'best position to understand the patient's needs and assess the risks and benefits of a particular course of treatment.'" Ames, 431 F.Supp.2d at 572 (quoting Lee, 721 F.Supp. at 95).[8] "A warning is legally adequate when it explains the risk which the plaintiff alleges has caused the injury." Lee, 721 F.Supp. at 95. "The warning must only be reasonable, not the best possible one." Ames, 431 F.Supp.2d at 572. Further, even if the warning is inadequate, "a failure to warn claim fails where the doctor was already aware of the risk the allegedly deficient warning should have communicated." Morris, 491 F.Supp.3d at 104.

The doctrine takes into account the learned intermediary's "entire field of knowledge" regarding the alleged risks; it is not restricted to the warnings provided by the manufacturer alone. Ames, 431 F.Supp.2d at 572. Maryland courts have recognized the learned intermediary doctrine in the context of prescription drugs, Gourdine, 955 A.2d at 776, and medical devices, Miller v. Bristol-Myers Squibb Co., 121 F.Supp.2d 831, 838

[8] The Restatement Third of Torts provides:

> (d) A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:
>
> (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or
>
> (2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.

Restatement (Third) of Torts: Prod. Liab. § 6(d) (1998).

(D.Md. 2000). Indeed, it is well settled that the learned intermediary doctrine applies in cases involving medical devices, like the TVT device used here. See Morris, 491 F.Supp.3d at 104 (citing cases).

Campbell argues first that the learned intermediary doctrine does not apply because Ethicon's warning was inadequate. (Opp'n at 10–12). She contends that Ethicon inadequately warned that patients with a history of back pain have a heightened risk of complications from TVT implantation. (Id. at 12).[9] Campbell points to Moorman's testimony that she "knew of no contraindication" between back pain and the TVT device. (Moorman Dep. at 108:17–23). Campbell argues that she would not have had the surgery if she had known about the risk.

The Court need not address the application of the learned intermediary doctrine here because Campbell's back pain argument fails from the outset. "Products liability law imposes on a manufacturer a duty to warn if the item produced has an inherent and hidden danger that the producer knows or should know could be a substantial factor in causing an injury." Morris, 491 F.Supp.3d at 103–04 (emphasis added) (quoting Shreve, 166 F.Supp.2d at 413); see Doe v. Miles Labs., Inc., 927 F.2d 187, 194 (4th Cir. 1991) (stating in a failure-to-warn case that a pharmaceutical manufacturer "must warn physicians . . . of risks known or reasonably foreseeable at the time the product is administered"). Here, Campbell has presented no evidence that Ethicon knew or should have known that a

[9] Again, the Court notes that although Campbell offhandedly references other risks, like "permanent" dyspareunia, she only consistently assesses the risk of complications in patients with back pain throughout her failure to warn arguments. (See Opp'n at 9–13).

clinical history of back pain could be a substantial factor in causing injury in patients implanted with the TVT device. Her own medical expert, Bruce Rosenzweig, does not opine that Ethicon knew or should have known that a history of back pain leads to an increased risk of complications following the implantation of a TVT device. (See Rosenzweig Gen. Rep. at 67–73). Indeed, his references to Campbell's back pain only appear within the context of her medical history and are not connected in any way to her ultimate rejection of the TVT device. (Rosenzweig Case-Specific Rep. at 4, 17). Rosenzweig cites no studies or data regarding the supposed risks affiliated with back pain to substantiate Campbell's implicit assertion that Ethicon knew or should have known of the risk.

Campbell's only purported support for her argument that Ethicon knew or should have known of the risks affiliated with back pain is pulled from a 2012 deposition of Dr. David Robinson, a Medical Director for Ethicon, taken in a New Jersey circuit court case regarding pelvic mesh. (David Robinson Dep. ["Robinson Dep."] at 509:1–25, ECF No. 74-4). In the deposition, Robinson concedes that patients with "pain condition[s]" are at an increased risk to suffer from pain after the implantation of a "Prolift" device. (Robinson Dep. at 509:15–25). This testimony is both unpersuasive and irrelevant to Campbell's case, which involves the implantation of an entirely different device, the TVT. As Campbell has failed to provide evidence that Ethicon knew or should have known of a risk that a history of back pain could be a substantial factor in causing an injury, she has failed to demonstrate that Ethicon had a duty to warn Moorman of that risk. At best, Campbell has succeeded in raising the mere "possibility" of a risk, but that alone is insufficient to trigger a duty to

warn regardless of whether the duty extends to the physician or the patient. See Miles Labs., 927 F.2d at 194 ("If pharmaceutical companies were required to warn of every suspected risk that could possibly attend the use of a drug, the consuming public would be so barraged with warnings that it would undermine the effectiveness of these warnings.").

Even if this Court were to consider the application of the learned intermediary doctrine here, Campbell's arguments are unconvincing. Campbell contends that the learned intermediary doctrine applies only in cases where the warning is found to be adequate, not in cases where the warning is inadequate. Campbell oversimplifies and misconstrues the law in this regard. Maryland courts have indeed applied the learned intermediary doctrine in cases where the warning was found to be inadequate. In Morris v. Biomet, this Court held that "even where a warning is inadequate, a failure to warn claim fails where the doctor was already aware of the risk the allegedly deficient warning should have communicated." 491 F.Supp.3d at 104. Accordingly, the doctrine applies both (a) where a warning is legally adequate and (b) where the warning is inadequate and the doctor was independently aware of the risk which allegedly caused plaintiff's injury. Again, Campbell's failure to warn claim does not make it this far because it is premised on a speculative risk, but even if that were not the case, the learned intermediary doctrine appears to apply.

Campbell argues next that even if the doctrine applies here, the Court should adopt a new rule in Maryland that if the adequacy of the warning is in question, "then proximate cause can be shown by proof other than the doctor's testimony that an adequate warning would have altered his or her prescribing behavior"—namely, Campbell's own testimony that she would not have moved forward with the procedure if she knew of the risks. (Opp'n

at 11). Campbell cites only one unpublished case from North Carolina in support of her position. See Fussman v. Novartis Pharms. Corp., No. 1:06CV149, 2011 WL 5836928 (M.D.N.C. Nov. 21, 2011). In Fussman, the court declined to overturn a jury's verdict in favor of the plaintiff on product liability claims, including failure to warn. The court noted that a North Carolina statute provided for an "affirmative defense" "where a prescription drug manufacturer provides an adequate warning to the prescribing physician." Id. at *8 (citing N.C. Gen. Stat. § 99B–5). The court indicated that the jury expressly rejected the defense and, in any event, concluded that the warning given to the plaintiff's physician was inadequate. Id. Fussman is both factually and legally inapposite, and the Court is unpersuaded that it supports Campbell's argument that the learned intermediary doctrine should be modified in Maryland.

Accordingly, Campbell has failed to demonstrate that Ethicon had a duty to warn her physician of the supposed increased risk of complications affiliated with the TVT implant in patients with a history of back pain. The Court will grant judgment in favor of Ethicon on Campbell's failure to warn claims. (Count I – in part; Count III; Count XIV – in part).

2. Design Defect

Ethicon argues that Campbell's design defect claim fails because she has not presented evidence of a feasible safer alternative design, which it contends is required to demonstrate that the product was unreasonably dangerous. (See Mot. at 16–22). At bottom,

the Court disagrees with Ethicon's application and will deny Ethicon's Motion as to Campbell's strict liability design defect claim. (Count V).[10]

"A products liability design defect claim 'focuses upon the specifications for the construction of the product and the risks and benefits associated with that design.'" Morris v. Biomet, Inc., 491 F.Supp.3d 87, 103 (D.Md. 2020) (quoting Shreve v. Sears, Roebuck & Co., 166 F.Supp.2d 378, 411 (D.Md. 2001)). The negligence theory "focuses on the conduct of the defendant." Id. (quoting Parker v. Allentown, Inc., 891 F.Supp.2d 773, 780 (D.Md. 2012)). Strict liability theory, on the other hand, focuses primarily on the product. Id. Both theories, however, require a showing of the same three elements, "defect, attribution of defect to the seller, and a causal relationship between the defect and the injury." Id. Accordingly, "the elements of proof are the same whether the claim [is] characterized as one for strict liability or negligence." McCoy v. Biomet Orthopedics, Inc., No. ELH-12-1436, 2021 WL 252556, at *22 (D.Md. Jan. 25, 2021) (quoting Heckman v. Ryder Truck Rental, Inc., 962 F.Supp.2d 792, 802 (D.Md. 2013)).

Proof of a defect "must arise above surmise, conjecture or speculation." Parker, 891 F.Supp.2d at 780 (quoting Virgil v. Kash N' Karry Serv. Corp., 484 A.2d 652, 657 (Md.Ct.Spec.App. 2005)). There is "significant overlap" between negligence theory and strict liability design defect as the claims "share the 'product litigation[] basics,' i.e., a

[10] Ethicon contends that its argument regarding whether the product was unreasonably dangerous extends to Campbell's design defect claims under both negligence and strict liability. As the Court will explain, Ethicon's argument pertains only to strict liability design defect. Accordingly, the Court shall only consider Ethicon's argument as it pertains to Count V, strict liability design defect, and not Campbell's negligence theory design defect claims. (Count I – in part & Count XIV – in part).

defect attributable to Defendant and a causal relationship between that defect and Plaintiff's injury." Id. (quoting Laing v. Volkswagen of Am., Inc., 949 A.2d 26, 39 (Md.Ct.Spec.App. 2008)).

Despite the overlap, negligence theory design defect and strict liability design defect have distinct elements. See Parker, 891 F.Supp.2d at 780. Negligence theory claims recall the familiar, well-known elements of negligence—duty, breach, proximate cause, and damages. Id. Under the negligence theory, the manufacturer must design and manufacture the product in a way that is safe for all reasonably foreseeable uses. Id. Strict liability design defect diverges from the negligence theory, however, as "duty, breach, and foreseeability are not elements of a strict liability claim." Id. at 781. Instead, the elements of strict liability design defect are:

> (1) the product was in a defective condition at the time that it left the possession or control of the seller, (2) that it was unreasonably dangerous to the user or consumer, (3) that the defect was a cause of the injuries, and (4) that the product was expected to and did reach the consumer without substantial change in its condition.

Id. (quoting Phipps v. Gen. Motors Co., 363 A.2d 955, 958 (Md. 1976)). Accordingly, "for a seller or manufacturer to be strictly liable for a design defect, the product must be both in a defective condition, as required in negligence and strict liability alike, and unreasonably dangerous at the time that it is placed on the market by the seller or manufacturer." Id. (quoting Phipps, 363 A.2d at 958) (cleaned up).

When determining whether a product is "defective and unreasonably dangerous, for strict liability purposes," the court will either apply the consumer expectation test[11] or the risk-utility test.[12] Parker, 891 F.Supp.2d at 791 (quoting Halliday v. Sturm, Ruger & Co., 792 A.2d 1145, 1150, 1152 (Md. 2002)). "The consumer expectation test asks whether the product was in a defective condition at the time it was sold." Lloyd v. Gen. Motors Corp., 275 F.R.D. 224, 228 (D.Md. 2011). "The risk-utility test asks 'whether a manufacturer,

[11] Under the consumer expectation test, a product is defectively dangerous "if it is dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchased it with the ordinary knowledge common to the community as to the product's characteristics." Halliday v. Sturm, Ruger & Co., 792 A.2d 1145, 1150 (Md. 2002) (quoting W. Page Keeton et al., Prosser and Keeton on the Law of Torts, § 99, at 698 (5th ed. 1984)).

[12] Under the risk-utility test, the court considers:

> (1) The usefulness and desirability of the product—its utility to the user and to the public as a whole.
> (2) The safety aspects of the product—the likelihood that it will cause injury, and the probable seriousness of the injury.
> (3) The availability of a substitute product which would meet the same need and not be as unsafe.
> (4) The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.
> (5) The user's ability to avoid danger by the exercise of care in the use of the product.
> (6) The user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or the existence of suitable warnings or instructions.
> (7) The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.

Parker, 891 F.Supp.2d at 791.

knowing the risks inherent in the product, acted reasonably in putting it on the market.'" Id. (citation omitted).

Ethicon advocates for the application of the risk-utility test, which, unlike the consumer expectation test, requires that the plaintiff produce evidence of a reasonably feasible alternative design. (Mot. at 16–17). It then contends that Campbell's design defect claim must fail because she has not produced sufficient evidence of an alternative design. The Court is unconvinced that the risk-utility test applies to Campbell's design defect claims.

As Ethicon acknowledges, the default test that Maryland courts apply in design defect cases is the consumer expectation test. See Simpson v. Standard Container Co., 527 A.2d 1337, 1340 (Md.Ct.Spec.App. 1987) ("To determine whether a product is defective in its design, Maryland cases have generally used the 'consumer expectation' test."); Ruark v. BMW of N. Am., LLC, No. ELH-09-2738, 2014 WL 1668917, at *6 (D.Md. April 24, 2014) (indicating that the Maryland Court of Appeals has adopted the consumer expectation test in all three cases in which it addressed the proper standard in a strict liability design defect case). The risk-utility test is the exception to the rule and "only applies in certain, limited circumstances—those in which a product malfunctions (i.e. performs in a manner other than how it was designed to perform)." Ruark, 2014 WL 1668917, at *8; see also Halliday, 792 A.2d at 1153 ("[T]he risk-utility test does not apply to a design defect unless the product malfunctions in some way."). In addressing the proper test to apply to a strict liability claim, the Maryland Court of Appeals has explained that a gun "does not malfunction when it shoots a bullet into a person in whose direction it is

fired." Halliday, 792 A.2d at 1153. Rather, in that case, the gun is operating as intended and designed and the consumer expectation test should apply. Id.; accord Ruark, 2014 WL 1668917, at *5. Products that courts have found malfunctioned, requiring the application of the risk-utility test, include an unbalanced machine that tipped over, a motor home that exploded, a power press that caught the user's hands, and a rack that tipped over. See Ruark, 2014 WL 1668917, at *5 (quoting Kelley v. R. G. Indus. Inc., 497 A.2d 1143, 1149 (Md. 1985)); Parker, 891 F.Supp.2d at 791. The risk-utility test "cannot be extended to impose liability on the maker or marketer" of a product which has not malfunctioned. Ruark, 2014 WL 1668917, at *5 (quoting Kelley, 497 A.2d at 1149).

Ethicon argues that the Court should apply the risk-utility test here because Campbell alleges that her TVT implant failed to perform as Ethicon intended, and therefore, it malfunctioned. (Mot. at 17). The Court disagrees. First, Campbell does not allege that her specific TVT device malfunctioned. Instead, she contends that "the materials used in its design are inherently flawed and that all pelvic mesh implanted in patients inevitably degrade[s] and erode[s] due to this defective design." (Opp'n at 17). Further, Ethicon does not identify any specific way in which the product failed to function as it was intended. Instead, Ethicon simply argues that the product was meant to treat stress urinary incontinence, not cause harm. (Mot. at 17).

Ethicon's construction does not follow the reasoning in Halliday. In its decision, the Court of Appeals pointed to several Court of Special Appeals cases where the intermediate court improperly used the risk-utility test when it should have used the consumer expectation test. Halliday, 792 A.2d at 1153; see C & K Lord v. Carter, 536 A.2d 699

(Md.Ct.Spec.App. 1988); Ziegler v. Kawasaki, 539 A.2d 701 (Md.Ct.Spec.App. 1988); Klein v. Sears, Roebuck & Co., 608 A.2d 1276 (Md.Ct.Spec.App. 1992); Nissan Motor Co. v. Nave, 740 A.2d 102 (Md.Ct.Spec.App. 1999). Nave is instructive.

In Nave, the plaintiff was driving a Nissan pickup truck when he crashed into a tractor-trailer. 740 A.2d at 104. As a result of the accident, Nave struck the steering column in the car and suffered from fatal chest injuries. Id. Nave's estate filed suit alleging that the steering column was designed defectively. Specifically, the plaintiffs claimed that the steering column should have compressed downward when Nave struck it and that it failed to absorb the force appropriately. Nissan, like Ethicon here, contended that the column was not defectively designed. Id. at 111. The Court of Special Appeals applied the risk-utility test and found that the plaintiffs had failed to provide sufficient evidence of an alternative design. Id. at 118–19, 127–28. The Court of Appeals in Halliday noted that the Court of Special Appeals was incorrect to apply the risk-utility test in Nave and should have applied the consumer expectation test. Halliday, 792 A.2d 1153.

The allegations and circumstances in Nave are similar to those presented here. The TVT product, like Nissan's steering column, was not designed or intended to cause harm. And Ethicon has not indicated that Campbell's TVT device failed to function as intended or designed in any way. Campbell, like the plaintiffs in Nave, argues that the product should have been designed more safely. As such, the consumer expectation test applies.

Ethicon argues that this Court recently applied the risk-utility test in an unpublished decision involving its pelvic mesh and urges a similar result. In Thompson v. Ethicon, Inc., No. SAG-19-3159, 2020 WL 3893253, *3–4 (D.Md. 2020), this Court considered whether

the learned intermediary doctrine applies to the consumer expectation test. The Court indicated that it did not need to reach the issue because the plaintiffs' design defect claims survived summary judgment under the risk-utility test. Id. at *4.

But as this Court noted in Thompson, the risk-utility test "applies when a product malfunctions in some way." Id. Here, Ethicon has not demonstrated that Campbell's TVT device malfunctioned and therefore has not provided grounds to apply the exception, the risk-utility test, rather than the general rule, the consumer expectation test. See Ruark, 2014 WL 1668917, at *2–6 (discussing the history of strict liability design defect standards under Maryland law). Accordingly, the consumer expectation test applies and Ethicon's arguments regarding Campbell's failure to meet the standard articulated under the risk-utility test are irrelevant. The Court will deny Ethicon's Motion as to Campbell's strict liability design defect claim. (Count V).

3. Fraud

Ethicon argues that the Court should dismiss Campbell's claims for fraud, fraudulent concealment, and negligent misrepresentation. (Counts VI, VII, IX) (Mot. at 13). At bottom, the Court agrees and will dismiss the claims.

To establish fraud, a plaintiff must show that

> (1) the defendant made a false representation to the plaintiff, (2) the falsity of the representation was either known to the defendant or the representation was made with reckless indifference to its truth, (3) the misrepresentation was made for the purpose of defrauding the plaintiff, (4) the plaintiff relied on the misrepresentation and had the right to rely on it, and (5) the plaintiff suffered compensable injury as a result of the misrepresentation.

Dierker v. Eagle Nat. Bank, 888 F.Supp.2d 645, 651 (D.Md. 2012) (quoting Hoffman v. Stamper, 867 A.2d 276, 292 (Md. 2005)). To establish fraudulent concealment, a plaintiff must show

> (1) the defendant owed a duty to the plaintiff to disclose a material fact; (2) the defendant failed to disclose that fact; (3) the defendant intended to defraud or deceive the plaintiff; (4) the plaintiff took action in justifiable reliance on the concealment; and (5) the plaintiff suffered damages as a result of the defendant's concealment.

Lawley v. Northam, No. ELH-10-1074, 2011 WL 6013279, at *9 (D.Md. Dec. 1, 2011) (quoting Lloyd v. Gen. Motors Corp., 916 A.2d 257, 274 (Md. 2007)). Finally, to establish negligent misrepresentation, a plaintiff must show

> (1) the defendant, owing a duty of care to the plaintiff, negligently asserts a false statement; (2) the defendant intends that his statement will be acted upon by the plaintiff; (3) the defendant has knowledge that the plaintiff will probably rely on the statement, which, if erroneous, will cause loss or injury; (4) the plaintiff, justifiably, takes action in reliance on the statement; and (5) the plaintiff suffers damage proximately caused by the defendant's negligence.

Id. (quoting Lloyd, 916 A.2d at 273).

Ethicon argues that the claims should be dismissed as duplicative of Campbell's failure to warn claims. (Id. at 13). Campbell responds by raising her earlier argument regarding back pain, asserting again that Moorman testified that if she had been informed

of the elevated risk for patients with prior back pain, she would have discussed those risks with Campbell.[13]

As explained above, Campbell has not produced evidence indicating that Ethicon knew or should have known of a contraindication relating to back pain—indeed, her own medical expert did not include such an opinion in either of his reports. Campbell's cursory responses to Ethicon's fraud arguments in her Opposition are unpersuasive. Accordingly, the Court will grant judgment as to Counts VI, VII, and IX.

4. Loss of Consortium

Finally, Ethicon argues that Mr. Campbell's loss of consortium claim (Count XVI) should be dismissed because it is derivative in nature and dependent on Ms. Campbell's success on her other claims. (Mot. at 21). Because Ethicon has requested summary judgment on all of Ms. Campbell's claims, it contends that the loss of consortium claim should be dismissed. (Id.). As the Court will deny Ethicon's Motion as to Ms. Campbell's design defect claims, Ms. Campbell still has active claims on which Mr. Campbell's loss of consortium claim may attach. See Rozinsky v. Assurance Co. of Am., No. RDB-15-2408, 2016 WL 927147, at *3 (D.Md. Mar. 4, 2016) (explaining that Maryland has permitted derivative loss of consortium claims tied to causes of action stemming from a spouse's personal injury). Accordingly, the Court will deny Ethicon's Motion as to Count XVI.

[13] The Court notes that Plaintiffs repeatedly refer to "Ms. Conway" in their Opposition. (See Opp'n at 14). The Court assumes that the briefing is intended to refer to "Ms. Campbell" in those instances.

III. CONCLUSION[14]

For the foregoing reasons, the Court will grant in part and deny in part Defendants' Motion for Summary Judgment (ECF No. 73). A separate Order follows.

Entered this 28th day of December, 2021.

/s/
George L. Russell, III
United States District Judge

[14] Ethicon argues in its Reply that the Campbells have abandoned their gross negligence claim by failing to address it in their Opposition. (Reply at 1 n.1). The Court agrees. Ethicon raises a specific, albeit brief, argument regarding Campbell's gross negligence claims in two footnotes. (Mot. at 7 n.2, 16 n.6). Campbell does not address gross negligence or otherwise respond to Ethicon's assertion that "[t]here is no admissible summary judgment evidence in the record to support Plaintiffs' claim that Ethicon acted wantonly or willfully to inflict injury intentionally or with indifference to Plaintiffs' rights, in its manufacture or marketing of TVT." (Id. at 7 n.2). Accordingly, Campbell has abandoned her claim for gross negligence and the Court will dismiss it. See Mentch v. E. Savings Bank, FSB, 949 F.Supp. 1236 (D.Md. 1997) (holding that by failing to respond to claims on summary judgment, the court may consider those claims abandoned).